CITROMA- magesium citrate liquid Cariba International

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Cariba 686

Active ingredient

Magnesium citrate 1.745 g per fl oz

Purpose

Saline Laxative

Use

for relief of occasional constipation (irregularity). Generally productes bowel movement in 1/2 to 6 hours.

Warnings

for this product

Ask a doctor before use

If you have

- kidney disease
- a magnesium or potassium-restricted diet
- abdominal pain, nausea, or vomiting
- noticed a sudden change in bowel habits that persists over a period of 2 weeks
- already used a laxative for a period longer than 1 week.

Ask a doctor or pharmacist before use

If you are taking any other drug. Take this product 2 or more hours before or after other durgs. Laxatives may affect how other durgs work.

Stop use and ask a doctor

If you have rectal bleeding or failure to have a bowel movement after use. These could be signs of serious condition.

If pregnant or breast-feeding

Ask a health professional before use.

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- drink a full glass (8 ounces) of liquid with each dose
- may be taken as a single dose or in divided doses

Adults and children 12 years and over - 6.5 to 10 fl oz maximum 10 fl oz in 24 hours children 6 to under 12 years of age - 3 to 7 fl oz maximum 7 fl oz in 24 hours children 2 to under 6 years of age - 2 to 3 fl oz maximum 3 fl oz in 24 hours children under 2 years of age - ask a doctor discard unused product within 24 hours of opening bottle

Other information

each fl oz contains: magnesium 290 mg

each fl oz contains: potassium 80 mg

inactive ingredients

citric acid, lemon oil, potassium bicarbonate, water purified, sodium saccharin

Adverse reactions

Distributed by:

Cariba International

P.O. Box 1208

Safety Harbor, Florida 34695

MADE IN USA WITH US AND FOREIGN COMPONENTS

Principal display panel

CARIBA

MAGNESIUM CITRATE

SALINE LAXATIVE

ORAL SOUTION

PLEASING LEMONY FLAVOR

PASTEURIZED

VERH LOW SODIUM

DO NOT USE IF TAMPER EVIDENT TWST-OFF CAP IS MISSING, BROKEN OR SEPRATED FROM NECKRING

10 FL OZ (296 mL)



CITROMA magesium citrate liquid Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:67860-686 Route of Administration ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MAGNESIUM CITRATE (UNII: RHO2601T9V) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM CITRATE	1.745 g in 29.61 mL

Inactive Ingredients		
Ingredient Name	Strength	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
LEMON OIL (UNII: 19GRO824LL)		
POTASSIUM BICARBONATE (UNII: HM5Z15LEBN)		
water (UNII: 059QF0KO0R)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:67860- 686-38	296 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product	12/20/2016	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part334	12/20/2016	

Labeler - Cariba International (049354067)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(67860-686)

Revised: 5/2022 Cariba International